

AMENDMENTS TO THE DRAWINGS:

The attached replacement sheet of drawings includes changes to Fig. 4 on sheet 4/4. Fig. 4 has been amended in order to show the four layer structure.

Attachments: Replacement Sheet [4/4, Fig. 4]

REMARKS

In the Office Action, dated November 30, 2007, the Examiner objected to the drawings under 37 CFR § 1.83(a) for failure to show every feature of the claimed invention; provisionally rejected claims 1, 2, 5-7, 20, and 21-25 for non-statutory obviousness-type double patenting over claims 1-6, 8-9, 14-16, and 30 of co-pending Application No. 10/539,409 to Buck et al. ("Buck") in view of non-patent publication "Transport and Mechanical properties of Hemodialysis Hollow Fibers" to Klein et al. ("Klein"); rejected claims 1-7 and 21-25 under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 4,882,223 to Aptel et al. ("Aptel") with incorporation by reference of U.S. Patent No. 3,615,024 to Michaels ("Michaels"); rejected claim 20 under 35 U.S.C. § 103(a) as being unpatentable over Aptel with incorporation by reference of Michaels in view of U.S. Patent No. 5,340,480 to Kawata et al. ("Kawata"); and rejected claims 1-7 and 21-25 under U.S.C. § 103(a) as being unpatentable over KR 2001-061733 to Kim et al. ("Kim") in view of one or more of Kawata, U.S. Patent No. 6,045,899 to Wang et al. ("Wang"), U.S. Patent No. 5,188,734 to Zepf ("Zepf"), U.S. Patent No. 4,664,669 to Ohyabu et al. ("Ohyabu"), U.S. Patent No. 5,075,003 to Aoyagi ("Aoyagi"), U.S. Patent No. 5,505,851 to Wagener et al. ("Wagener"), and U.S. Patent No. 6,890,435 to Ji et al. ("Ji").

By this Reply, Applicant has amended claims 1, 3, and 4, and has cancelled claims 2, 22, and 23. Accordingly, claims 1, 3-7, 21, 24, and 25 are currently pending in this application. No new matter has been added by this Reply.

OBJECTION TO DRAWINGS

The Examiner objected to the drawings under 37 CFR § 1.83(a), for failure to show every feature of the claimed invention. Specifically, the Examiner indicated that

"the 4-layer structure must be shown." (Office Action at 2.) With this Reply and pursuant to 37 CFR § 1.121(d), Applicant has provided a replacement sheet of drawings identifying the boundaries of each of the layers of the 4-layer structure. Applicant requests that Examiner withdraw the objection to the drawings.

DOUBLE PATENTING

As noted above, the Examiner also rejected claims 1, 2, 5-7, 20, and 21-25 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8-9, 14-16, and 30 of Buck in view of Klein. Applicant respectfully disagrees with the assertions made by the Examiner in formulating the provisional obviousness-type double patenting rejections set forth at pages 3-5 of the Office Action. In order to expedite prosecution of this application, however, Applicant submits herewith a Terminal Disclaimer to obviate the provisional double patenting rejections. The filing of the Terminal Disclaimer in no way manifests an admission by Applicant as to the propriety of the double patenting rejections. See M.P.E.P. § 804.02 citing Quad Environmental Technologies Corp. v. Union Sanitary District, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991). Applicant reserves the right to traverse the provisional double patenting rejections at a later date. Applicant respectfully requests the withdrawal of the double-patenting rejection in view of the Terminal Disclaimer attached hereto.

REJECTION UNDER § 102(b)

In the Office Action, the Examiner rejected claims 1-7 and 21-25 under 35 U.S.C. § 102 as being anticipated by Apte with incorporation by reference of Michaels. Applicant traverses and requests the withdrawal of the § 102(b) rejection of claims 1-7,

21, 24, and 25 as amended (claims 22 and 23 having been cancelled) for at least the following reasons.

In order to incorporate a second document by reference, a first document must “[e]xpress a clear intent to incorporate by reference by using the root words ‘incorporat(e)’ and ‘reference’” and “clearly identify the referenced patent, application, or publication.” *See* 37 C.F.R. § 1.57.

Aptel refers to Michaels by stating “[f]ibers having such a structure are disclosed for example in U.S.A. Pat. Nos. 3,526,588, 3,615,024, 3,423,491.” Aptel, col. 1, ll. 29-31. Aptel, however, does not use the words “incorporate” or “reference” in conjunction with the reference to Michaels, and thus does not incorporate Michaels by reference.

Furthermore, neither Aptel nor Michaels anticipates Applicant’s claims. In order to properly anticipate Applicant’s claims under § 102, a single prior art reference must disclose each and every element of the claim at issue, either expressly or under principles of inherency. Further, “[t]he identical invention must be shown in as complete detail as is contained in the. . . claim.” *See* M.P.E.P. § 2131. Also, “[t]he elements must be arranged as required by the claim.” *Id.* Applicant respectfully requests withdrawal of the rejection for the reasons provided below.

Aptel discloses a hollow fiber having an outer skin with “a very low thickness lower than 0.1 μm and is permeable to water with a substantial absence of pores having a diameter higher than 1000 Å.” (Aptel, col. 2, ll. 32-34.) Aptel, however, does not disclose “a fourth outer layer in the form of a sponge layer having an outer surface having pores with sizes in the range of 0.5-3 μm ,” as recited in independent claim 1 (noting that 1000 Å is equivalent to 0.1 μm).

Michaels discloses a flat sheet membrane having a "layer of 'skin'... in which the average pore diameter is in the millimicron range, for example from 1.0 to 1000 millimicrons." (Michaels, col. 3, ll. 26-29.) Michaels also discloses tables related to the water flux values across a membrane. (Michaels col. 14, ll. 65-72 & col. 15, ll. 10-29.) Neither Michaels nor Aptel, however, discloses "said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm²" as recited in independent claim 1.

In the Office Action, the Examiner states that "[t]he plurality of pores in the skin layer ({Michaels} Claim 1) can easily be used to extrapolate the overlapping density of pores given the pore size and water flux of the hollow fiber membranes as reported using the diameter of the pores and volume of water fluxed ({Michaels} Tables 15 & 16)." (Office Action at 6.) Applicant disagrees.

To establish inherency, "the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." See M.P.E.P. § 2112(IV) *citing Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

Applicant disagrees with the Examiner's contention that "the plurality of pores in the skin layer ... can easily be used to extrapolate the overlapping density of pores given the pore size and water flux." (Office Action at 6.) For example, the water flux is dependent not just on the density and size of the pores on the outer surface of the membrane, but also on the density and size of pores of other layers of the membrane. Furthermore, even if an argument exists that one may be able to determine a density of

pores on the outer surface using a disclosed pore size and water flux value, this does not mean that the “characteristic necessarily flows from the teachings of the applied prior art.” Accordingly, neither Michaels nor Aptel discloses “said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm²” as recited in independent claim 1.

For at least the aforementioned reasons, independent claim 1 is allowable over the cited references, and thus, the § 102(b) rejection of independent claim 1 as amended, should be withdrawn. Further, claims 2-7, 21, 24, and 25 are allowable over the cited references at least due to their dependence, either directly or indirectly, from allowable independent claim 1. Accordingly, the rejection of claims 2-7, 21, 24, and 25 should also be withdrawn (claims 22 and 23 having been cancelled).

REJECTION UNDER § 103(a)

In the Office Action, the Examiner also rejected claim 20 under 35 U.S.C. § 103(a) as being unpatentable over Aptel with incorporation by reference of Michaels in view of Kawata.

Claim 20 ultimately depends from independent claim 1. As discussed above in connection with claim 1, Aptel does not use the words “incorporate” or “reference” in conjunction with the reference to Michaels, and thus does not incorporate Michaels by reference.

Furthermore, as discussed above, neither Aptel nor Michaels discloses “said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm²” as recited in independent claim 1.

Kawata discloses hollow fiber membranes for hemodialysis, hemofiltration, and hemoconcentration, however Kawata does not disclose “pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm²ⁿ” as recited in independent claim 1. Thus, Kawata does not cure the deficiencies of Aptel and Michaels discussed above. Therefore, claim 20 is allowable over the cited references, and thus, the § 103(a) rejection of dependent claim 20 should be withdrawn.

ADDITIONAL REJECTIONS UNDER § 103(a)

In the Office Action, the Examiner further rejected claims 1, 2, 4-7 and 22-25 under 35 U.S.C. § 103(a) as being unpatentable over Kim in view of Kawata, Wang, or Zepf; claims 3, 20, and 21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kim as applied to claims 1 and 2 in view of Kawata; and claims 6 and 7 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kim as applied to claim 2 in view of Kawata, Ohyabu, Aoyagi, Wagener, or Ji. Applicant traverses these rejections.

“The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. . . . [R]ejections on obviousness cannot be sustained with mere conclusory statements.” M.P.E.P. § 2142, 8th Ed., Rev. 6 (Sept. 2007) (internal citation and inner quotation omitted). “The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art.” M.P.E.P. §2143.01(III) (emphasis in original). “In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the

claimed invention as a whole would have been obvious.” M.P.E.P. § 2141.02(I),
(emphasis in original).

Several basic factual inquiries must be made in order to determine the obviousness or non-obviousness of claims of a patent application under 35 U.S.C. § 103. These factual inquiries, set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 U.S.P.Q. 459, 467 (1966), require the Examiner to:

- (1) Determine the scope and content of the prior art;
- (2) Ascertain the differences between the prior art and the claims in issue;
- (3) Resolve the level of ordinary skill in the pertinent art; and
- (4) Evaluate evidence of secondary considerations.

The obviousness or non-obviousness of the claimed invention is then evaluated in view of the results of these inquiries. *Graham*, 383 U.S. at 17-18, 148 U.S.P.Q. at 467; see also *KSR Internat'l Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385 (U.S. 2007); see also M.P.E.P. § 2141(II).

REJECTION OF CLAIMS 1, 2, 4-7 & 22-25

Applicant traverses the Examiner's rejection of claims 1, 2, 4-7, and 22-25 under 35 U.S.C. § 103(a) as being unpatentable over Kim in view of Kawata, Wang, or Zepf. Kim discloses a "hollow fiber membrane ... comprised of the inner surface layer (D), the intermediate layer (C), and the boundary layer (B) existing between the outer surface layer (A), the intermediate layer and outer surface layer." (Kim, trans. ¶ 20.) Kawata discloses that "use have been made of polymers such as cellulose-based, cellulose acetate-based, polyamide-based, polyacrylonitrile-based, polyvinyl alcohol-based,

polymethyl methacrylate-based, polysulfone-based, polyolefin-based or the like.”

(Kawata, col. 1, ll. 24-28.)

Kim and Kawata, however, do not teach a hollow fiber membrane having an outer sponge layer, wherein “the number of said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm^2 ” as recited in claim 1. The Examiner contends, however, that Wang discloses that “[p]ore density in the skin is about 15 per 1000- μm^2 .” (Office Action at 11.) Wang, however, similarly fails to teach a hollow fiber membrane having an outer sponge layer, wherein “the number of said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm^2 ” as recited in claim 1.

The membrane of Wang is a flat sheet membrane and not a “hollow fiber membrane,” as recited in claim 1. The problems with scrape resulting during the manufacture of hollow fiber membranes, due to the hollow fiber membranes sticking together and knocking into each other, are not present in the manufacturing process of flat sheet membranes, as disclosed in Wang. Wang does not disclose or suggest any connection between the pore density and a reduction in the amount of scrape or contact within a membrane during manufacturing. In fact, the tendency of hollow fiber membranes to rupture during manufacturing, the likelihood of which is reduced by the claimed invention, is not a matter of concern when manufacturing flat membranes. Accordingly, one of ordinary skill in the art would not have been motivated to combine the flat sheet membrane of Wang, including its pore density, with the hollow fibrous membrane of Kim.

Furthermore, the minimum pore surface of Wang is the selective surface giving the separation features to the membrane. In the membrane of the instant application, however, the separation layer is on the inside of the hollow fiber, while the pore density feature belongs to the outer surface of the hollow fiber.

Also, during the manufacture of the hollow fiber membrane of Kim, an inside coagulant liquid is used as well as an external condensation liquid. Thus, there is a large difference between the manufacture of the hollow fibers of Kim and the manufacture of the claimed hollow fibers. Kim uses an external liquid which surrounds the fiber coming out of the nozzle. This is not comparable to the controlled atmosphere used in the manufacture of the claimed hollow fiber membrane, which gives it the unique claimed outer surface. The unique claimed outer surface leads to a reduction in the amount of scrape during manufacturing of the hollow fiber and reduces the tendency for rupture of such membranes.

Thus, for at least the reasons discussed above, claim 1 is allowable over the cited references.

The Examiner alleges that Zepf teaches “that the flow rate is controlled by pore and density population of skin pores including such membrane designs having graded pore density.” (Office Action at 11.) Zepf, however, does not cure the deficiencies of Wang and Kim discussed above. Therefore, claims 4-7, 24, and 25, which depend from claim 1, are allowable over the prior art (claims 22 and 23 having been cancelled).

REJECTION OF CLAIMS 3, 20, AND 21

Applicant traverses the Examiner’s rejection of claims 3, 20, and 21 under 35 U.S.C. § 103(a) as being unpatentable over Kim in view of Kawata. As discussed

above, Kim discloses a “hollow fiber membrane ... comprised of the inner surface layer (D), the intermediate layer (C), and the boundary layer (B) existing between the outer surface layer (A), the intermediate layer and outer surface layer.” Kim, trans. ¶ 20. Examiner alleges that Kawata teaches “hydrophobic/hydrophilic polysulfone-based hollow fiber membranes for dialysis ... or hemodialysis, hemofiltration, and hemoconcentration.” (Office Action at 13.)

Kim and Kawata do not, however, teach a hollow fiber membrane having an outer sponge layer, wherein “the number of said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm²” as recited in claim 1, from which claims 3, 20, and 21 depend. Thus, claims 3, 20, and 21 are allowable over the cited references at least due to their dependence from allowable independent claim 1 and due to their additional recitations of novel subject matter. Accordingly, the rejection of claims 3, 20, and 21 should be withdrawn.

REJECTION OF CLAIMS 6 & 7

Applicant traverses the Examiner’s rejection of claims 6 and 7 under 35 U.S.C. § 103(a) as being unpatentable over Kim in view of Kawata, Ohyabu, Aoyagi, Wagener, or Ji. As discussed above, Kim discloses a “hollow fiber membrane ... comprised of the inner surface layer (D), the intermediate layer (C), and the boundary layer (B) existing between the outer surface layer (A), the intermediate layer and outer surface layer.” Kim, trans. ¶ 20. The Examiner alleges that Kawata teaches “polysulfone hollow fiber membranes for blood filtration and teaches background materials for selective permeable membranes to be polyolefin-based, polyfulfene-based, and polyamide-based” (Office Action at 14) and “polysulfone hollow fiber membranes for blood

filtration" (Office Action at 15). The Examiner also alleges that Wagner teaches "polyaramides, polyamides, and cellulose and copolymers" for "semipermeable membranes of sulfonated polymers." (Office Action at 14-15.) The Examiner further alleges that Aoyagi teaches "polyurethane, polyolefin, polypropylene, polyamide, and polysulfone polymer tapes." (Office Action at 15.) The Examiner finally alleges that Ji teaches "hollow fiber microfiltration membranes with a range of hydrophilic polymers including polyethylene oxide, polyamides, cellulose, and polyvinylpyrrolidone." (Office Action at 15.) Applicant did not find where Examiner relied upon Ohyabu for a specific teaching.

Wagner, Aoyagi, Ohyabu, and Ji do not teach, however, a hollow fiber membrane having an outer sponge layer, wherein "the number of said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm²" as recited in independent claim 1, from which claims 6 and 7 depend. Thus, claims 6 and 7 are allowable over the cited references at least due to their dependence from allowable independent claim 1 and due to their additional recitations of novel subject matter. Accordingly, the rejection of claims 6 and 7 should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: February 28, 2008

By: /Aaron L. Parker/
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Attachments: **Replacement Sheet [4/4, Fig. 4]**